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EXAMINER	
FISHER, ABIGAIL L	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
02/25/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/030,300	WACHTER ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 18 2009 has been entered.

Receipt of Amendments/Remarks filed on December 18 2009. Claims **1-11** are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Specification

The disclosure is objected to because of the following informalities: there are various misspellings in the specification. Specifically, obtained (page 1, line 7), substantially (page 3, line 14), hexamethylene (page 4, line 2), formula (page 4, line 3), pectin (page 5, line 14), synthetic (page 5, line 14), antiperspirants (page 5, line 28) and addition (page 6, line 20). Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 7-8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. (US Patent No. 4895724, cited in the Office action mailed on 4/15/05) in view of Vanderhoff et al. (US Patent No. 6214331, cited in the Office action mailed on 9/3/08).

Applicant Claims

Applicants claim a collagen free cosmetic preparation which can be obtained by cross-linking of solutions of chitosans and β-(1,3) glucans with diisocyanates and/or dialdehydes.

Applicants claim a method of preparing collagen free cosmetic preparations comprising admixing a solution which an aqueous solution of β-(1,3) adding a cross-linking agent selected from the group consisting of diisocyanates and dialdehydes and removing water from the mixture.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Cardinal et al. teach a porous matrix comprising chitosan and a dispersed molecule (abstract). The compositions of the invention are useful when injected or implanted. Examples of macromolecular pharmacological compounds include polysaccharides such as heparin and dextrin (column 2, line 21). A chitosan molecular weight of 100K-2M is specified (column 2 lines 56-59). Dissolution of chitosan and the macromolecule are disclosed (column 3 lines 12-14, 41-44). It is taught that protein stabilizer such as sugars can be incorporated (column 3, lines 65-68). Drying at low temperature under a vacuum is disclosed (column 4 lines 14-16). The chitosan may

be crosslinked either before or after loading of the matrix with the macromolecule (column 4, lines 59-62). Crosslinking agents taught include glutaraldehyde as well oxidized polysaccharides such as dextran dialdehyde and starch dialdehyde (column 5, lines 3-18).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Cardinal et al. do not specify that the polysaccharide utilized is a β-(1,3) glucans such as curdlan. However, this deficiency is cured by Vanderhoff et al.

Vanderhoff et al. is directed to the process for the preparation of aqueous dispersion of particles of water-soluble polymers. The particles of the invention are use for implantation (abstract). Examples of water soluble polymers include polysaccharides (column 8, lines 22-23). Example of natural polysaccharides include national polysaccharides such as curdlan (β-(1,3) glucan), dextran, and heparin (column 8, lines 32-37). Functional groups of the water soluble polymers include aldehydes (column 8, line 19). It is taught that these polymers can be crosslinked with crosslinking reagents such as glutaraldehyde (column 8, lines 58).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Cardinal et al. and Vanderhoff et al. and utilize curdlan as the polysaccharide in the invention of Cardinal et al. One of ordinary skill in the art would have been motivated to utilize curdlan as the macromolecule in the invention of Cardinal et al. as Cardinal et al. teach that polysaccharides such as dextran and heparin can be

utilized as the macromolecule and Vanderhoff et al. teach that curdlan, dextran and heparin are all examples of natural polysaccharides. Alternatively, one of ordinary skill in the art would have been motivated utilize curdlan dialdehyde as Cardinal et al. teach that one type of crosslinking agent is dextran dialdehyde and Vanderhoff et al. teach that the polysaccharides can comprise functional groups such as aldehydes. One of ordinary skill in the art would have been motivated to replace dextran with curdlan as both are taught by Vanderhoff et al. as functional equivalents.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. in view of Vanderhoff et al. and in further view of Moriguchi et al. (US Patent No. 4879340, cited in the Office action mailed on 4/15/05).

Applicant Claims

Applicant claims that the diisocyanates and dialdehydes are represented by the following formulas: O=CN-[X]-NC=O and OHC-[Y]-CHO wherein X and Y represent a linear or branched naphthenic or aromatic hydrocarbon residue with 1 to 12 carbon atoms.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Cardinal et al. and Vanderhoff et al. are set forth above. Specifically Cardinal et al. teach compositions comprising dextran and chitosan which are crosslinked with agents such as gluteraldehyde. Vanderhoff et al. teach that curdlan and dextran are functional equivalents.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Cardinal et al. do not teach crosslinking agents of the claimed formulas. However, this deficiency is cured by Moriguchi et al.

Moriguchi et al. is directed to porous beads of chitosan. It is taught that crosslinked chitosan has superior chemical characteristics such as acid resistance and mechanical strength. Crosslinking agent utilized for crosslinking chitosan include dialdehydes and diisocyanates comprising a cyclohexylene, phenylene, methylphenylene or dimethyphenylene group (column 4, lines 9-34).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Cardinal et al., Vanderhoff et al., and Moriguchi et al. and utilize the crosslinking agents of Moriguchi et al. One of ordinary skill in the art would have been motivated to utilize these crosslinking agents as Moriguchi et al. teach they are crosslinking agents of chitosan that results in chitosan having superior chemical characteristics and mechanical strength.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. in view of Vanderhoff et al. and in further view of Martin et al. (US Patent No. 6162537, cited in the Office action mailed on 9/3/08).

Applicant Claims

Applicant claims that natural and/or synthetic fibers are added to the mixture.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Cardinal et al. and Vanderhoff et al. are set forth above. Specifically Cardinal et al. teach compositions comprising dextran and chitosan which are crosslinked. The compositions are utilized for injection or implantation. Vanderhoff et al. teach that curdlan and dextran are functional equivalents.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Cardinal et al. do not specify that natural and/or synthetic fibers are added. However, this deficiency is cured by Martin et al.

Martin et al. is directed to implantable fibers. It is taught that synthetic materials are known to be useful in the manufacture of many implantable articles. The more useful ones are fibers formed from synthetic polymers (column 1, lines 27-28). These fibers are often highly desirable for many implantable applications because of their mechanical properties. Furthermore, the fibers ability to be engineered into useful

structures and the resulting product being able to retain these mechanical properties under conditions of the human body can be desirable (column 1, lines 33-35).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Cardinal et al. and Martin et al. and utilize synthetic polymer fibers in the invention of Cardinal et al. One of ordinary skill in the art would have been motivated to add these fibers because Cardinal et al. is directed to implantable material and Martin et al. teach that synthetic polymer fibers are desirable for implantable applications because of their mechanical properties.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cardinal et al. in view of Vanderhoff et al. and in further view of Liu et al. (US Patent No. 6096344, cited in the Office action mailed on 9/3/08).

Applicant Claims

Applicant claims that the water is removed from the mixture by freeze-drying.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Cardinal et al. and Vanderhoff et al. are set forth above. Specifically Cardinal et al. teach porous compositions comprising dextran and chitosan which are crosslinked. Drying at low temperature under a vacuum is disclosed. Vanderhoff et al. teach that curdlan and dextran are functional equivalents.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Cardinal et al. do not specify that the drying is conducted by freeze-drying. However, this deficiency is cured by Liu et al.

Liu et al. is directed to bioerodible porous compositions which comprise a porous network (abstract). It is taught that controlled dehydration via lyophilization, which is the same as freeze-drying, is preferred to avoid collapsing the porous network (column 5, lines 18-27).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Cardinal et al., Vanderhoff et al., and Liu et al. and utilize freeze-drying as the method for drying the composition. One of ordinary skill in the art would have been motivated to utilize freeze-drying because Cardinal et al. teach that drying at low temperature under a vacuum and Liu et al. teach that lyophilization allows for drying without collapsing the porous composition.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that the claims of the present application are directed to composition comprising chitosans cross-linked to glucans through diisocyanates or dialdehydes where as Cardinal's compositions comprise cross-linked chitosans with macromolecular compound dispersed therein.

Applicants' arguments filed December 18 2009 have been fully considered but they are not persuasive.

Firstly, the examiner would like to address the claims as currently written and their interpretation. Claim 1 recites a preparation comprising swollen aqueous solutions of chitosans and beta-(1,3) glucans cross-linked with diisocyanates, dialdehydes or combination thereof. One interpretation of this claim, based on the way it is written, is that only the glucans are cross-linked with the diisocyanates and dialdehydes. There is nothing in the claim that requires **both** the chitosan and glucans to be crosslinked with diisocyanates or dialdehydes or that both be cross-linked to the same diisocyanates or dialdehydes. Regarding the claim method (claim 2), the claims require two steps. The first step is admixing an aqueous solution of chitosans with beta-(1,3)-glucans and then adding a crosslinking agent following by water removal. There is no requirement (or step) in the claim that the glucans and chitosan are cross-linked through diisocyanates and dialdehydes. The limitations of the claim are met if the two steps are taught in the prior art.

Cardinal teaches that crosslinking agents include dialdehyde versions of sugar and curdlan dialdehyde is taught by Vanderhoff et al. which would read on glucans crosslinked with dialdehydes.

Cardinal teaches (and Applicant agrees on page 8 of the response) that Cardinal teaches that the chitosan can be cross-linked either before or after the loading of the matrix with the macromolecule. Therefore, Cardinal teaches the admixing the macromolecule and chitosan which is step one of the method claims. Then crosslinking would require the addition of a cross-linking agent and therefore, Cardinal teaches both claimed steps which are admixing and adding a cross-linking agent. There is nothing in the claims that require any particular type of reaction to happen or any specific type of compound to form. Therefore, Cardinal's teachings of cross-linked chitosan matrix with macromolecules dispersed therein would read on claim 2 and those claims that depend from claim 2.

Regarding claim 11, as interpreted by the examiner the claims require chitosan crosslinked and beta-glucans crosslinked. However, the claims do not require that the chitosan be crosslinked to the beta-glucans through diisocyanates, dialdehydes or combinations thereof. Therefore, a composition comprising chitosan crosslinked with glutaraldehyde and beta-glucan dialdehyde would read on the instant claims.

It appears applicants are arguing a specific formula for the resulting chitosans and glucans. However, the instant claims do not reflect this particular formula or the structure applicants argue is claimed (specifically that the chitosans are cross-linked to

glucans through diisocyanates or dialdehydes. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 9643066 (cited on PTO Form 1449) in view of Adachi et al. (Chem. Pharm. Bull. 1990).

Applicant Claims

Applicants claim a collagen free cosmetic preparation which can be obtained by cross-linking of solutions of chitosans and β-(1,3) glucans with diisocyanates and/or dialdehydes.

Applicants claim a method of preparing collagen free cosmetic preparations comprising admixing a solution which an aqueous solution of β-(1,3) adding a cross-linking agent selected from the group consisting of diisocyanates and dialdehydes and removing water from the mixture.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

DE '066 (citations are directed to the machine translation) is directed to a collagen free cosmetic preparation. It is formed by crosslinking cationic biopolymers with polyols and diisocyanates and/or dialdehydes followed by water removal (page 1, 5th paragraph). Cationic biopolymers taught include chitosan (page 1, paragraph 8). Crosslinking agents taught include diisocyanates which have the formula O=CN[X]-

NC=O and dialdehydes which have the formula OHC-[Y]-CHO. Examples include glutaraldehyde (page 2, crosslinking agent section). It is taught that for the mechanical properties of the fleeces, it has been shown to be of advantage to add natural and synthetic fibers (page 2, paragraph 7). As exemplified the water is removed by freeze-drying. It is taught that surfactants that can be added to the formulation. Examples of surfactants include polyols and polyalkylene glycols (page 3, number 6 and 13).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

DE '066 does not teach that the polyol is a beta-(1,3)-glucan. However, this deficiency is cured by Adachi et al.

Adachi et al. is directed to macrophage activation *in vitro* by chemically crosslinked beta-(1,3)-glucans. It is taught that beta-(1,3)-glucans are anti-tumor and posses gel-forming ability. It is taught that crosslinking of these glucans is important for the manifestation of biological activities (page 988, first paragraph).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of DE '066 and Adachi et al. and utilize beta-glucans as the polyol component of the composition. One of ordinary skill in the art would have been motivated to beta-glucans as they are known polyols which possess anti-tumor activity and whose biological activity is manifested upon cross-linking. Therefore, since DE '066 teach utilizing polyols for crosslinking to chitosan with additional crosslinking agents such as dialdehydes and diisocyanates, one of ordinary

skill in the art would have been motivated to utilize beta-glucans in order to provide anti-tumor activity to the compositions as taught by Adachi et al.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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